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10/551,101	09/26/2005	Richard Mueller	ZP192-05009	1624

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EXAMINER	
WOODALL, NICHOLAS W	
ART UNIT	PAPER NUMBER
3775	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,101	MUELLER, RICHARD	
	Examiner	Art Unit	
	Nicholas Woodall	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10,11,13-59 and 61-68* is/are pending in the application.

4a) Of the above claim(s) *16-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10,11,13,14,55-59 and 61-68* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on December 23, 2009.

2. Claims 4 and 11 are objected to because of the following informalities: claims 4 and 11 both state that the lower cap further comprises an extension of a lower semi-cylindrical surface residing within the channel. Claim 1 states that the lower cap includes a first lower semi-cylindrical surface that engages the rod and an extension positioned with the channel having a second lower semi-cylindrical surface. Since the extension is positioned within the channel the lower semi-cylindrical surface already has a portion located in the channel making the limitations of claims 4 and 11 duplicate limitations. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 10, 11, 13-15, 55-59, and 61-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 4 recites the limitation "...further comprises an extension of said lower semi-cylindrical surface..." in lines 1-2. Claim 1 states the lower cap includes two lower semi-cylindrical surfaces, the first semi-cylindrical surface and the second semi-cylindrical surface, and the claim is unclear which semi-cylindrical surface is being

referenced. The examiner will interpret the semi-cylindrical surface of claim 4 as reference the second lower semi-cylindrical surface for examination purposes.

6. Claim 10 recites the limitation "...further comprising a head disposed at said distal end..." in line 2. Claim 1 states the distal end of the bone screw engages a bone making the claim unclear. The examiner will interpret the head of the screw being disposed at the proximal end of the bone screw for examination purposes.

7. Claim 11 recites the limitation "...further comprises an extension of said lower semi-cylindrical surface..." in lines 1-2. Claim 1 states the lower cap includes two lower semi-cylindrical surfaces, the first semi-cylindrical surface and the second semi-cylindrical surface, and the claim is unclear which semi-cylindrical surface is being referenced. The examiner will interpret the semi-cylindrical surface of claim 11 as reference the second lower semi-cylindrical surface for examination purposes.

8. Claim 55 recites the limitation "...wherein said extension member protrudes from other structure of said lower cap..." in lines 15-16. The claim is unclear on what "other structure" references and is not clear as to the location the extension member protrudes from the lower cap. The examiner will interpret the limitation as the extension member protrudes from the lower cap for examination purposes.

9. Claim 62 recites the limitation "...wherein said extension member protrudes from other structure of said lower cap..." in lines 8-9. The claim is unclear on what "other structure" references and is not clear as to the location the extension member protrudes from the lower cap. The examiner will interpret the limitation as the extension member protrudes from the lower cap for examination purposes.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-4, 10, 11, 55-59, and 61-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Vienney (WO 03/024343) and in view of Puno (U.S. Patent 5,360,431).

Barker discloses a device (see Figure 7 for an example) comprising a polyaxial bone screw (50), a rod (R) having a diameter defining a first dimension, a housing (30, 70, 90, etc.), and a locking assembly (120). The bone screw includes a proximal end that engages a driving device and a distal end that engages bone. The proximal end of the bone screw includes a head having an aspheric upper surface, i.e. the specification discloses the upper surface of the head may only have knurls or a roughened surface (column 5 lines 43-45) proving an aspheric surface, i.e. not perfectly sphere shaped. The housing is coupled to the proximal end of the bone screw and includes opposing spaced apart flanges that extend longitudinally and define a channel that receive the rod. The flanges include an outer surface and an inner surface with female threads on a portion of the inner surface. The locking assembly locks the rod to the housing in contact with the proximal end of the bone screw. The rod is inserted into the channel of the housing and the locking assembly is inserted into the channel of the housing, wherein a driving instrument is inserted into the cavity of the locking assembly and

rotates the locking assembly thereby engaging at least a portion of a male thread with the female threads of the housing causing the locking assembly to translate longitudinally into the housing and in contact with the rod, which forces the rod into a locked relationship with the proximal end of the bone screw to prevent angular movement of the bone screw relative to the housing (see column 8 lines 28-37). Barker fails to disclose the device having a locking assembly that includes an upper cap and a lower cap and the lower cap of the locking assembly including an extension.

Regarding the locking assembly including an upper cap and a lower cap, Barker discloses a device comprising a locking assembly as discussed above. Vienney teaches a device (see Figure 1 for an example) comprising a bone anchor integrally formed with a housing having an inner surface with female threads, a rod, and a locking assembly, wherein the locking assembly includes an upper cap (4) having male threads (41) and an inner cavity having a second profile passing through the upper cap from a upper surface to a lower surface that includes an opening to receive a post (33) having a first profile that is geometrically similar to the second profile (see Figure 5), a lower cap (3) having a lower semi-cylindrical surface that engages the rod, wherein the post joins the upper cap to the lower cap and allows free rotational movement of the caps relative to one another such that a driving instrument inserted into the inner cavity rotates the upper cap relative to the lower cap about the post to engage the male threads with the female threads to longitudinally translate the locking assembly within the housing and into contact with the rod in order to force the rod into a locked relationship with the housing. Because both Barker and Vienney teach devices including locking assemblies

positioned within a housing to force a rod into a locked relationship with the housing, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one locking assembly for the other in order to achieve the predictable results of forcing a rod into a locked relationship with the housing.

Regarding the lower cap including an extension, Puno teaches a device (see Figures 4-7 for an example) comprising a bone anchor, a housing including opposing flanges defining a channel, and a locking assembly, wherein the locking assembly includes an upper cap (27) and a lower cap (25) having a semi-cylindrical surface (72) that engages a rod and an integral extension (46/47) that protrudes from the lower cap into the channel of the housing and includes an extension of the semi-cylindrical surface in order to help align the lower cap relative to the rod. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Barker as modified by Vienney wherein the lower cap further includes an extension in view of Puno in order to help align the lower cap relative to the rod.

Regarding the upper cap and the lower cap being received within the housing in no more than two orientations, the Puno reference discloses the lower cap having two extension that help align the lower cap with the rod and will only allow the lower cap into the housing if the extensions are aligned within the channel, which also allows the upper cap to only engage the threads of the housing when the lower cap is properly aligned with the housing. Therefore, the device of Barker as modified by Vienney as further modified by Puno discloses a device wherein the lower cap can inserted into the housing in no more than two orientations.

Regarding the post being symmetrical about a longitudinal axis/plane, the claims are not specific on which longitudinal axis/plane the post is symmetrical about. Vienney teaches a post that has a longitudinal axis/plane that is perpendicular to the longitudinal axis/plane of the rod. Therefore, the device of Barker as modified by Vienney as further modified by Puno discloses a device wherein the post is symmetrical about a longitudinal axis/plane.

Regarding the post being asymmetrical about a longitudinal axis/plane, the claims are not specific on which longitudinal axis/plane the post is asymmetrical about. Vienney teaches a lower cap having a longitudinal axis/plane that is parallel with the longitudinal axis/plane of the rod and can be interpreted as further including a longitudinal axis/plane that is offset from the longitudinal axis of the lower cap at a distance equal to the height of the lip on the post, wherein the post would be asymmetrical about the offset axis/plane. Therefore, the device of Barker as modified by Vienney as further modified by Puno discloses a device wherein the post is asymmetrical about a longitudinal axis/plane.

12. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Vienney (WO 03/024343) further in view of Puno (U.S. Patent 5,360,431) further in view of Tsou (U.S. Patent 5,176,678).

The device of Barker as modified by Vienney as further modified by Puno discloses the invention as claimed except for the bone anchor comprising a hook. The device of Barker as modified by Vienney as further modified by Puno discloses a device comprising a bone screw as discussed above. Tsou teaches a device comprising a

bone anchor, a rod, a housing, and a locking assembly, wherein the bone anchor can be either a polyaxial bone screw or a polyaxial hook in order to anchor the device to a bone. Because both the device of Barker as modified by Vienney as further modified by Puno and the device of Tsou both disclose bone anchors for anchoring a device to a bone, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one bone anchor, i.e. a bone screw, for the other, i.e. a hook, in order to achieve the predictable results of anchoring the device to a bone.

13. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker (U.S. Patent 6,660,004) in view of Vienney (WO 03/024343) further in view of Puno (U.S. Patent 5,360,431) further in view of Katz (U.S. Patent 5,989,254).

The device of Barker as modified by Vienney as further modified by Puno discloses the invention as claimed except for the proximal end of the bone screw further comprising a depression disposed about the periphery, i.e. intersection of the upper and lower surfaces of the head of the bone screw and the inner cavity further comprising an appurtenance projecting substantially radially inward. Katz teaches a device (see Figure 1) comprising a bone screw with a head, a rod, a locking assembly with a lower cap (16) and an upper cap (15), and a housing including flanges defining a channel and an inner cavity, wherein the bone screw head further includes a depression disposed about a periphery of the head and the inner cavity further includes an appurtenance that projects substantially radially inward into the depression in order to retain the housing on the screw during implantation (see column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

provide the device of Barker as modified by Vienney as further modified by Puno wherein the head of the bone screw further comprises a depression and the inner cavity of the housing further comprises an appurtenance in view of Katz in order to retain the housing on the screw during implantation.

Allowable Subject Matter

14. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

15. Applicant's arguments, see pages 21-23, filed December 23rd, 2009, with respect to the rejection(s) of claim(s) 55-59 and 61-68 under 35 U.S.C. 103(a) have been fully considered and are persuasive, i.e. the applicant's argument that Yuan teaches away from substituting the flanges for threads as taught by Vienney was found persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references to Barker, Vienney, and Puno as discussed above. Claims 1-4, 6-8, 10, 11, and 13-15 were not rejected with prior art in the previous office action, but the examiner has provided a new grounds of rejection for claims 1-4, 6-8, 10, 11, and 13-15 above. The examiner has provided new grounds of rejection not necessitated by the amendment making this office action non-final.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775